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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/325,603	06/03/1999	ALLAN SVENDSEN	4394.214-US	3011

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EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT PAPER NUMBER

1652

DATE MAILED: 05/14/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/325,603

Applicant(s)

SVENDSEN ET AL.

Examiner

Elizabeth Slobodyansky

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 81-83 and 86-92 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 81-83 and 86-92 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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DETAILED ACTION

The amendment filed March 4, 2002 canceling claims 84 and 85, amending claims 81, 83 and 86 and adding claims 87-92 has been entered.

Claims 81-83 and 86-92 are pending.

Specification

The disclosure is objected to because of the following: Appendix 1 is present in the file as a separate entity and it does not have a title. The specification should be amended to insert it into the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 87 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim recites "amino acid residue or structural part within 10 Å of calcium or sodium ions". While the specification has support for "amino acid residue or structural

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part within 10 Å of calcium ions" (e.g., page 23, lines 22-24), the examiner is unable to locate adequate support in the specification for "amino acid residue or structural part within 10 Å of sodium ions". Thus there is no indication that residues within 10 Å of sodium ions were within the scope of the invention as conceived by Applicants at the time the application was filed.

Accordingly, Applicants are required to cancel the new matter in the response to this Office Action.

Claims 87-92 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing a variant of a parent α -amylase having a sequence of at least 70% homology to SEQ ID NO:13 by modeling the parent α -amylase on three-dimensional structure of α -amylase of SEQ ID NO:13, does not reasonably provide enablement for a method of producing a variant of a parent α -amylase of any structure by modeling the parent α -amylase on three-dimensional structure of α -amylase of SEQ ID NO:13. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of

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direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Factors pertinent to this discussion include predictability of the art, guidance in the specification, breadth of claims, and the amount of experimentation that would be necessary to use the invention.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of amylases having amino acid sequences with low or no homology to SEQ ID NO:13.

The claimed methods are based on the comparison of a structure at least 70% homologous to SEQ ID NO: 13 with the three-dimensional structure of the latter. A parent amylase while being highly homologous to SEQ ID NO:13 has some different properties resulted from the difference in the structures. Adjusting the structure of a parent amylase comprising residues of interest creates the structure with desired properties. It is essential that the structure of the parent amylase is highly homologous to the structure of SEQ ID NO:13. The specification does not provide guidance as to how to model the parent amylase with low or no homology to SEQ ID NO:13. Adjusting the few specific residues could result in an unpredictable change in function and properties of the entire molecule.

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Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which structure would impart the desired activity requires a detailed knowledge of the ways in which the proteins' structure relates to its function and vice versa, in general, the state of the art does not allow the predictability of function based on a structure. However, in this case the disclosure lacks any information regarding the correlation between function and structure of amylases with low or no homology to SEQ ID NO:13.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to use the claimed invention in a manner reasonably correlated with the scope of the claims broadly extending a method for producing a variant to a parent amylase of any structure. Without such guidance, the experimentation left to those skilled in the art is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 87-92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 87-92(a) recite "generating a model of a three-dimensional structure of a parent alpha-amylase, wherein said three-dimensional alpha amylase structure

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comprises ... defined by atomic coordinates of Appendix 1". It is not pointed out how the model is generated. Further, it is confusing because it reads on a parent alpha amylase that is a hybrid molecule comprising the residues of the amylase having coordinates defined in Appendix 1. The claims are further vague as omitting the reference to the structure of SEQ ID NO:13 that has said coordinates.

Double Patenting

Claims 81-83 and 86-92 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 5,989,169. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are claiming common subject matter, as follows: a method for producing a variant of a parent alpha-amylase having 70% homology to SEQ ID NO:13 using three-dimensional structure of SEQ ID NO:13 depicted in Appendix.

Applicants consideration for filing a TD stated in Remarks filed March 4, 2002, page 11, is noted. The claims stand rejected until a TD is filed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP §

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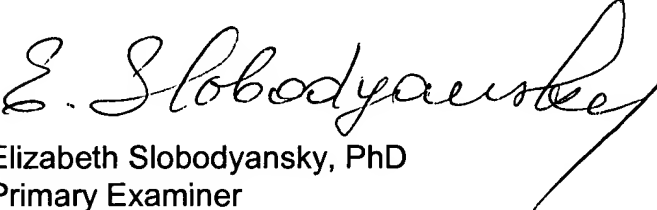
706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.


Elizabeth Slobodyansky, PhD
Primary Examiner